Standards Overview

CDR Scott Colburn
Director, Standards Management Staff
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Learning Objectives

- Give key definitions of standards
- Overview and history of the US National Standards Strategy
- Discuss the evolution and importance of standards at FDA and CDRH
- Explain the types of standards products that are recognized
- Discuss how standards are used in CDRH

Definition of a Standard

The term "standard" or "technical standard" as cited in the Food, Drug & Cosmetic Act, includes all of the following:

- Common and repeated use of rules, conditions, guidelines or characteristics for products or related processes and production methods, and related management systems practices.

Definition Continued:

The term “standard” also includes:

- The definition of terms; classification or components, delineation of procedures; specification or dimensions, materials, performance, design, or operations; measurement of quality and quantity in describing materials, processes, products, systems, services, or practices; test methods and sampling procedures; or descriptions and measurement of size or strength

Definition of a Voluntary Consensus Standard

…a "voluntary consensus standard is a standard developed or adopted by voluntary consensus standards bodies, both domestic and international.

US National Strategy

- Passage of the National Technology Transfer and Advancement Act (NTTAA) of 1995
- Signed into law March 7, 1996
- Grew out DoD's experience of relying more on voluntary consensus standards and less on Military Specifications (MIL SPECs)

NTTAA Objective

- Directs Federal Agencies to adopt private sector standards in lieu of creating proprietary, non-consensus standards

- Encourages Agency participation in voluntary consensus standards bodies

NTTAA

NTTAA brought civilian agencies, like FDA, into the practice of using private sector standards in place of government unique standards.

References

National Technology Transfer and Advancement Act

http://www.nist.gov/standardsgov/nttaa-act.cfm

Standards.gov

http://www.nist.gov/standardsgov/index.cfm

OMB Circular A-119

- OMB = Office of Management and Budget
- OMB establishes policies on:
  - Federal use and development of voluntary consensus standards
  - Conformity assessment activities

OMB Circular A-119

- Sets forth requirements for Agency participation
- Includes reporting requirements
- Sets forth requirements for incorporation of standards into Agency regulations

OMB Circular A-119 Goals

- Eliminate Government costs
- Provide incentives that serve national needs
- Encourage long-term growth for the US
- Promote economic competition

NIST

- NIST = National Institute of Standards and Technology
- Works with US industry, standards developers, other government agencies to build a standards infrastructure
- Monitors and participates in standards development and conformity assessment

References

OMB Circular A-119:
http://www.nist.gov/standardsgov/omba119.cfm

National Institutes of Standards and Technology:
http://www.nist.gov/

FDA & Standards

- 21 CFR 10.95, Participation in outside standard-setting activities
- FDA Policy regarding the development and use of standards with respect to international harmonization of regulatory requirements and guidelines, 60 FR 53078 (Oct. 11, 1995)
- FDA Staff Manual Guide 9100.1 (adopted March 2007)

International Harmonization

FDA Goals

- Safeguard US public health
- Assure that consumer protection standards and requirements are met
- Facilitate the availability of safe and effective products
- Develop and utilize product standards
- Minimize or eliminate inconsistent standards internationally

Standards at FDA

- SMG 9100.1 FDA Staff Manual Guides, Volume IV – Agency Program Directives
  - Common Standards
  - Development and Use of Standards
  - Definitions
  - Roles/Representation
  - Based on various Federal policies and regulations

FDA SMG 9100.1

- Recognize by reference either in its entirety or in part standards developed by SDOs
- FDA will preferentially use internationally harmonized standards
- Guidances published by FDA will, wherever appropriate, reference standards
- FDA encourages sponsors of product applications and manufactures to cite standards
- FDA incorporates voluntary consensus standards

References

International Harmonization; Policy on Standards; Notice http://www.gpo.gov/fdsys/granule/FR-1995-10-11/95-25070

FDA SMG 9100.1: http://www.fda.gov/aboutfda/reportsmanualsforms/staffmanualguides/ucm193332.htm

Standards in CDRH

- Medical Device Amendments of 1976
  - USC 514
- Safe Medical Device Act of 1990
  - Promulgation of mandatory standards at the Agency's discretion

Standards in CDRH

- FDA Modernization Act of 1997
  - Revised Section 514(c)
  - Added ability to formally recognize a standard, “all or in part”
  - Added the ability to accept a formal Declaration of Conformity

"Recognize"

The term "recognize" in section 514(c) of the FD&C Act refers to FDA's identification of standards as appropriate for manufacturers of medical devices to declare conformance to meet relevant requirements in the FD&C Act, including premarket submission requirements.

21 USC Section 514(c)

(c) Recognition of standard

(1)(A)…"by publication in the FR, recognize all or part of an appropriate standard established by a nationally or internationally recognized standard development organization for which a person may submit a declaration of conformity in order to meet a premarket requirement or other applicable requirement under this chapter to which such standard is applicable"

21 USC 514(c) – cont'd

(1)(B) If a person elects to use a standard recognized by the Secretary under subparagraph (A) to meet the requirements described in such subparagraph, the person shall provide a declaration of conformity to the Secretary that certifies that the device is in conformity with such standard. A person may elect to use data, or information, other than data required by a standard recognized under subparagraph (A) to meet any requirement regarding devices under this chapter.

21 USC 514(c) – cont'd

(2) The Secretary may withdraw such recognition of a standard through publication of a notice in the Federal Register if the Secretary determines that the standard is no longer appropriate for meeting a requirement regarding devices under this chapter.

21 USC Section 514(c)

(3)(A) Subject to subparagraph (B), the Secretary shall accept a declaration of conformity that a device is in conformity with a standard recognized under paragraph (1) unless the Secretary finds—

- (i) that the data or information submitted to support such declaration does not demonstrate that the device is in conformity with the standard identified in the declaration of conformity; or
- (ii) that the standard identified in the declaration of conformity is not applicable to the particular device under review.

Declaration of Conformity

- Used for FDA-recognized standards
- Certification that the device conforms to all of the requirements of an FDA-recognized standard
- In a DoC a submitter may not deviate from the FDA-recognized standard

Importance of Standards at FDA

- Gives CDRH discretion to use standards in any of our processes
- Builds consistency, credibility, and predictability
- Are integral in execution of CDRH mission:
  - Performance characteristics
  - Testing methods
  - Manufacturing practices

Importance of Standards at FDA

- Product specifications
- Scientific protocols
- Practice guidelines
- Compliance criteria
- Statistical methods
- Labeling
- Risk assessment

Types of Standards

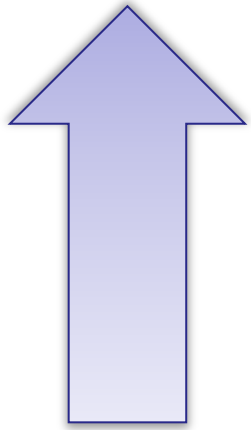
- Vertical
- Test Methods
- Material Specification
- Horizontal
- National
- International

Vertical Standards

- Applies to terminology, safety and/or performance aspects of specific devices or device groupings
- Specific procedures for evaluating these aspects are proscribed
- Make reference as far as possible to horizontal standards
- # recognized: approx. several hundred

Example:

ANSI/AAMI/IEC 60601-2-25 Ed. 2.0 2011-10 Medical electrical equipment – Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs



Test Methods

- A definitive procedure that produces a test result.
- The result of the test may be used to access compliance with a standard specification.
- # recognized: approximately 100

Procedure

1 → 2 → 3

Example:

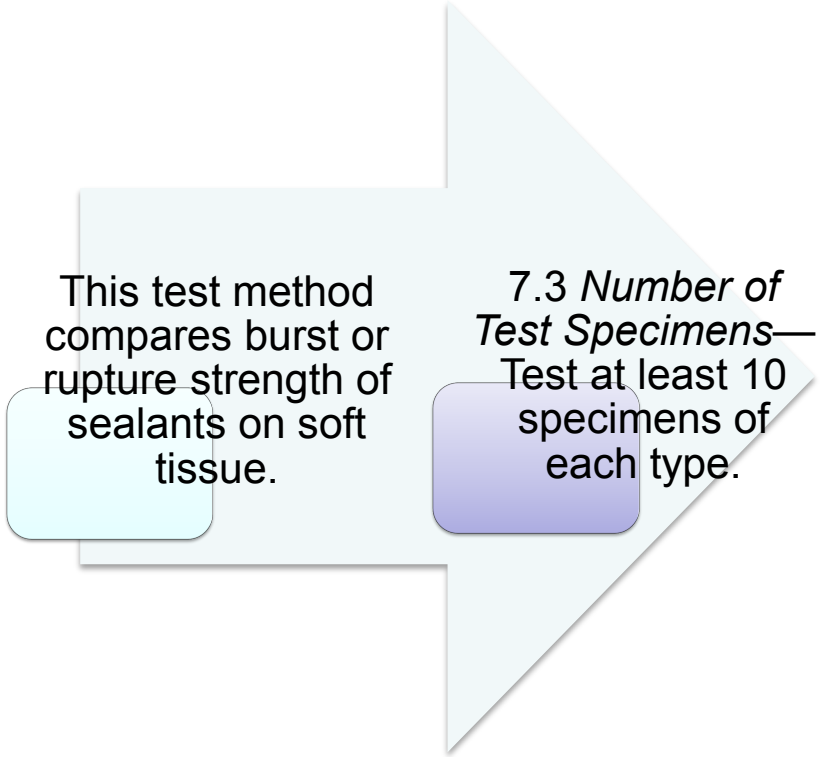
CLSI M43-A Methods For Antimicrobial Susceptibility Testing for Human Mycoplasmas

Material Specification

An explicit set of requirements to be satisfied by a material, product, system or service.

Typically includes requirements for physical, mechanical, or chemical properties, and safety, quality or performance criteria.

Example:
ASTM F2392-04(2010) Standard Test Method For Burst Strength of Surgical Sealants



Sterilization

Horizontal Standard

- Can be applied across a wide ranges of devices and device types.
- Built in flexibility: used across a range products or processes
- General principles and guidelines are laid out but details are left up to the user
- May also be defined as those standards that apply when a condition is not covered by a vertical standard.
- # recognized: approx 500

Example:

ISO 11135:2014 Sterilization of health care products – Ethylene Oxide – Requirements for the development, validation, and routine monitoring of a sterilization process for medical devices.

National Standards

- Designated as an “ANS” or American National Standard
- Developed by a US standards developing organization
- Accredited through ANSI
- Example: ANSI/AAMI ES60601-1

International Standards

- Developed by an international standards developing organization
- Examples:
  - ISO
  - IEC

US Adoption of International Standards

- International standard that is adopted in parallel with the international SDO

or

- International standard that is adopted with changes or deviations

Other Standards Products

Standard Practice - Defines a sequence of operations, that unlike a Test Method, does not produce a result. Examples: selection, preparation, application, etc.

Guide or Guideline – An organized collection of information or series of options that does not recommend a specific course of action

Practice - A set of instructions for performing one or more specific operations that does not produce a test result.

Standards Utilization

- CDRH believes that conformance with recognized consensus standards can support a reasonable assurance of safety and/or effectiveness for many applicable aspects of medical devices.

- Information submitted on conformance with such standards should have a direct bearing on safety and effectiveness determinations made for premarket submissions.

Standards Utilization – cont'd

- ✓ Be aware, the use of consensus standards generally satisfies only one part of a premarket submission
- ✓ It may not, on its own, provide sufficient basis for a regulatory decision
- ✓ It usually does not satisfy all the required elements of a submission
- ✓ FDA recognition of a standard does not supersede other aspects of the FD&C Act and its implementing regulations for marketing or investigating medical devices in the US.

Use in Premarket Submissions

- Traditional 510(k)
- Abbreviated 510(k)
- Special 510(k)
- *de novo*
- IDE
- PMA/PDP
- HDE
- Q Submission
- applicable CBER biological products (INDs and BLA)

Use in 510(k) Submssions

- In 510(k) submissions, conformance to a recognized consensus standard may help establish substantial equivalence of a new device to a predicate device.
- This information may be used to show that the new device is as safe and effective as the predicate in the area(s) covered by the standard.
- Note: → Not limited to 510(k)

Summary

1. We learned the definition of and different types of standards.
2. We reviewed the key pieces of legislation that formed the basis of the U.S. National Standards Strategy.
3. We discussed the evolution of standards as used by FDA.
4. We reviewed how standards are used by FDA and for what types of submissions they may be used.